

26, Applicants have amended claims 1 and 2 to recite that i, m, and t is 0 or 1 of the general formulas (1) and (2) with the proviso that i and t cannot be both 0. Support for the proviso is supported by the specification because all the Examples require the presence at least one of variable X or the moiety

$$\begin{array}{c} T \\ | \\ \neg(N-Z) \end{array}$$
 in the compositions of the present invention.

Notably, all of the independent claims 1-4 have been amended to overcome various indefiniteness rejections directed to a structural group or moiety due to allegedly confusing language. No new matter has been added by the amendments to claims 1-4 given that the amendments are solely related to clarifying allegedly confusing language. Moreover, and in response to the indefiniteness rejections, claims 1-3 have been amended to remove the phrase "n-mucin type synthetic compounds or it's carrier conjugated compounds, which have above mentioned compounds as a core structure of antigen". Dependent claims 17-28 are also amended into proper format to recite "compounds" in line with the independent claims from which they depend.

New claim 61 depending from claim 1 recites a non-mucin synthesized compound-carrier conjugated embodiment. The subject matter of dependent claim 61 is directed to the compound of the

general formula (1) of claim 1 conjugated with a pharmaceutically effective carrier. Support for the conjugated embodiment can be found in the specification on page 5, line 1. No new matter within the meaning of § 132 has been added by any of the amendments.

Accordingly, Applicants respectfully request the Examiner to enter the claim amendments, reconsider and withdraw the rejections and allow all claims pending in this application in view of the following remarks.

1. Rejection of Claims 1-4
under 35 U.S.C. § 112, ¶ 2

The Office Action rejects claims 1-4 under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office Action states:

Claims 1-4, claim a compound of general formula (1), (2), (3) and (4), respectively. Each of the general formulas contains the structural group or



moiety C, where Q is H or oxygen. However, this structural moiety or group renders the claim confusing and indefinite, because when

Q is hydrogen, the structural moiety or group would represent a double bond between carbon and hydrogen. But, since hydrogen can only form one bond, a double bond cannot be formed between carbon and hydrogen.

Claims 2, 3, 3, 17-28 recite the phrase "non-mucin type synthetic compounds or it's carrier conjugated compounds". However, this phrase "carrier conjugated compounds" renders the claim indefinite, because this phrase or terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what compounds are considered carrier conjugated compounds.

Applicants respectfully traverse the rejection. However, for the sole purpose of advancing prosecution wherein the amendment is in no way related to a substantial question of patentability, Applicants have amended claims 1-4 to reflect that the variable Q can be present or not present.

In particular, it appears that the Office Action is taking issue with the fact that a double bond cannot exist between Q and C when Q is hydrogen. Therefore, the Office Action rejects claims 1-4 as being indefinite for showing a double bond between the variable Q and C because Q is recited as being hydrogen or oxygen. Since it is understood that the carbon atom attached to the variable Q would have two hydrogen bonds in the absence of

oxygen, Applicants have amended claims 1-4 to recite that Q is oxygen and can be present or not present.

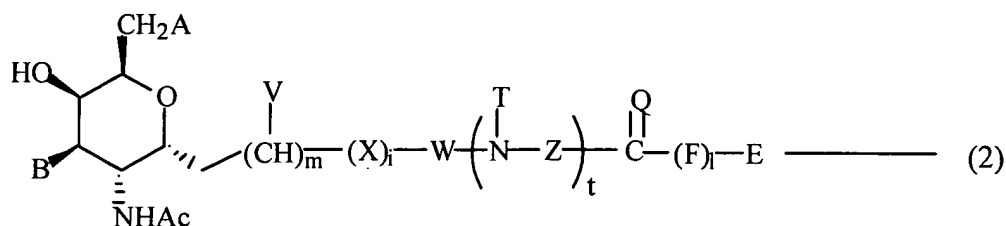
The Office Action further rejects claims 1-3 and 17-28 as also being indefinite for reciting the phrase, "or it's carrier conjugated compounds". Applicants have now deleted this phrase from the independent claims without prejudice or any disclaimer as to the subject matter contained therein. Notably, new dependent claim 61 recite the carrier conjugated compounds.

Accordingly, Applicants respectfully submit that all the presently pending claims particularly point out and distinctly claim the subject matter of the invention and request that the Examiner reconsider and withdraw the rejection under § 112, ¶ 2.

2. Rejection of Claims 2 and 26
under 35 U.S.C. § 102(a)

The Office Action rejects claims 2 and 26 under 35 U.S.C. §102(a) as anticipated by Tetrahedron Asymmetry (2000), 11(1), 295-303 ("Cipolla et al."). The Office Action states:

In claim 2, applicant claims a compound of general formula (2),



wherein A, B, T, X, Q, V, W, Z, i, m, and t have above-mentioned meanings; E represents pharmaceutically acceptable carrier compounds; 1 is 0 or 1;.... Cipolla et al. disclose applicant's claimed compound of general formula (2) wherein A represents OH, B=OH, m=0, i=w=t=0, Q=O and E represents a pharmaceutically acceptable carrier compound, and 1 is 0. Cipolla et al. compound is named D-glycero-L-gluco-2-Nonulose, 5-(acetylamino)-4,8-anhydro-1,3,5-trideoxy-(see compound 16, page 298). Claim 26 which is drawn to non-mucin type synthetic compounds or carrier conjugated compounds thereof of claim 2, wherein both A and B are OH, is also anticipated by this rejection. It should be noted that the examiner considers the methyl group an acceptable carrier compounds.

Applicants respectfully traverse the anticipation rejection because Cipolla et al. does not teach each and every claimed limitation of the amended independent claim 2 and dependent claim 26. In particular, Cipolla et al. fails to teach the claimed compound of the general formula (2) because a heteroatom need not be present in the side chains disclosed by Cipolla et al. In contrast, amended claim 2 recites that i, m, and t is 0 or 1 with the proviso that i and t cannot be both 0. Therefore,

either the variable X or the moiety $\overset{\text{T}}{\underset{|}{\text{---N-Z}}}$ **must** be present in the claimed compositions.

Turning to the rule regarding a rejection under § 102, the Federal Circuit held that anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Those elements must be expressly disclosed as in the claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). The Federal Circuit also ruled that the prior art reference must also be enabling, thereby placing the allegedly disclosed matter in the possession of the public. In re Brown, 241 U.S.P.Q. 245, 249 (C.C.P.A. 1964). In order to accomplish this, the reference must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it pertains could construct and use it. Id. at 250.

In the present application, claim 2 recites a compound of the general formula (2),

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present. Specifically, claim 2 recites that i and t which modify the variable X and the moiety $\leftarrow NT-Z$, respectively are both 0 or 1 with the proviso that i and t cannot be both 0 at the same time.

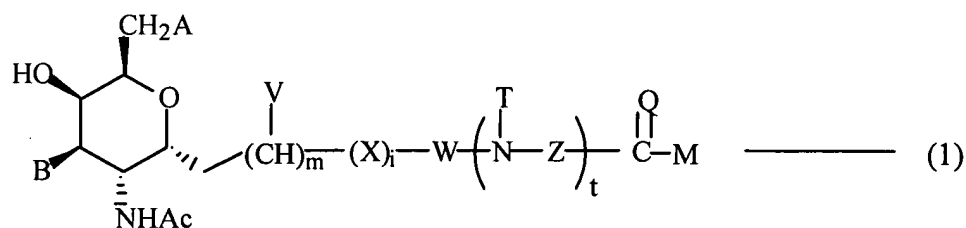
Given the complete and utter lack of any teaching regarding the presently claimed compounds, one of ordinary skill would not have been able to make the presently claimed compound of the general formula (2) without the expenditure of his own inventive effort in order to produce the presently claimed compositions.

Accordingly, Applicants respectfully submit that the presently claimed invention is not anticipated by Cipolla et al. and respectfully request the Examiner to reconsider and withdraw the § 102(b) rejection over claims 2 and 26.

3. Rejection of Claims 1 and 21
under 35 U.S.C. § 103(a)

The Office Action rejects claims 1 and 21 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,977,079 ("Good et al."). The Office Action states:

In Claim 1, applicant claims a compound of general formula (1),



wherein A represents OH or sialic acid...; non-mucin type synthetic compounds or it's carrier conjugated compounds, which have above mentioned compounds as a core structure of antigen.

Good et al. teach a subgenus that is fully embraced by the instant claim. Good et al. disclose in fig. IG (sheet 7, compound 35) a subgenus wherein in X represents a covalent bond and Y represents a radical of the general formula -A-Z wherein A is $-(\text{CH}_2\text{-CR}_1\text{-G})_n$ wherein n equal 1, R_1 is hydrogen, G is hydrogen and Z is $-\text{C}(\text{O})\text{OR}_2$ wherein R_2 is hydrogen (col. 7, lines 41 to 60). In addition, Good et al. disclose that such a carbohydrate can be used as xenoantigen (see col. 6, lines 63-64).

Good et al. fail to recite a specific compound but suggest a compound that read on the claimed invention (fig. IG, sheet 7, compound 35 and col. 7, lines 41 to 60).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared any compound suggested by the subgenus of Good et al., in order to use them as antigens.

One having ordinary skill in the art would have been motivated, to prepare any compound of a subgenus with a reasonable expectation that the compounds would have the utility of the subgenus as a whole. Therefore one

skilled in the art would have been motivated to make specific compounds of the subgenus of Good et al. in order to use them as antigens. It should be noted that claim 21 which is a limitation of claim 1 is also encompassed by this rejection.

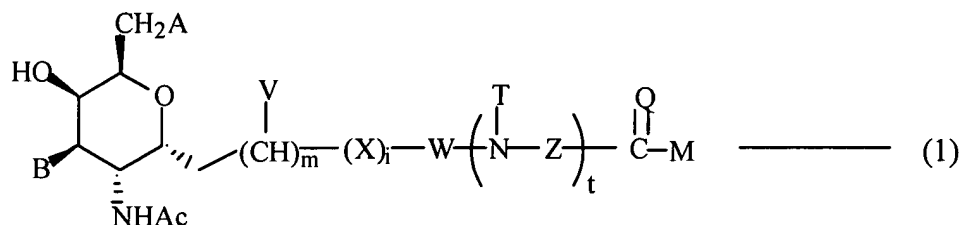
Applicants respectfully traverse the obviousness rejection because Good et al. does not satisfy the first prong of the *prima facie* test. In particular, Good et al. fails to teach the claimed compound of the general formula (1) because a heteroatom need not be present in the side chains disclosed by Good et al. In contrast, amended claim 1 recites that i, m, and t is 0 or 1 with the proviso that i and t cannot be both 0. Therefore,

T
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either the variable X or the moiety $-(N-Z)$ **must** be present in the claimed compositions.

Turning to the rule, the Federal Circuit held that a *prima facie* case of obviousness must establish: (1) some suggestion or motivation to modify the references; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

In the present application, claim 1 recites a compound of the general formula (1),



wherein

- A represents OH or sialic acid and/or it's derivatives, and
- B represents OH or galactose and/or it's derivatives;
- T represents H or protecting groups of amine;
- X represents oxygen atom, -NH- or S(O)_z (where z is 0, 1 or 2);
- Q is oxygen atom and can be present or not present;
- V represents lower alkyl or H;
- W is straight or branched alkylene groups from 0 to 5;
- Z is straight or branched alkylene groups from 1 to 5;
- i, m, and t is 0 or 1 **with the proviso that i and t cannot be both 0.**

Good et al. clearly fails to teach this compound. Although the Office Action alleges that compound 35 in Fig. 1G on sheet 7 of 19 is a sub-species of compound that is fully embraced by the

instant claim 1, Applicants respectfully traverse this assertion. While the symbol X of compound 35 of Good et al. does indeed represent a covalent bond and Y represents a radical of the general formula -A-Z wherein A is $-(CH_2-CR_1-G)_n-$ wherein n equal 1, R_1 is hydrogen, G is hydrogen and Z is $-C(O)OR_2$ wherein R_2 is hydrogen (col. 7, lines 41 to 60), the compound 35 very clearly shows an oxygen connecting the cyclic alkyl groups.

In contrast, the presently claimed compound of the general formula (2) specifically recites that either the variable X represented by oxygen, $-NH-$ or $S(O)_2$ or the moiety $(-NT-Z)$ must be present. Specifically, claim 1 recites that i and t which modify the variable X and the moiety $(-NT-Z)$, respectively are both 0 or 1 with the proviso that i and t cannot be both 0 at the same time. Clearly, one of ordinary skill in the art would not have had any motivation to modify the compounds of Good et al. in order to produce the presently claimed compounds.

Accordingly, Applicants respectfully submit that the presently claimed invention is not rendered obvious by Good et al. and respectfully request the Examiner to reconsider and withdraw the § 103(a) rejection over claims 1 and 21.

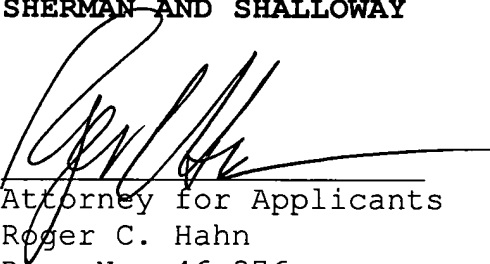
CONCLUSION

In light of the foregoing, Applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

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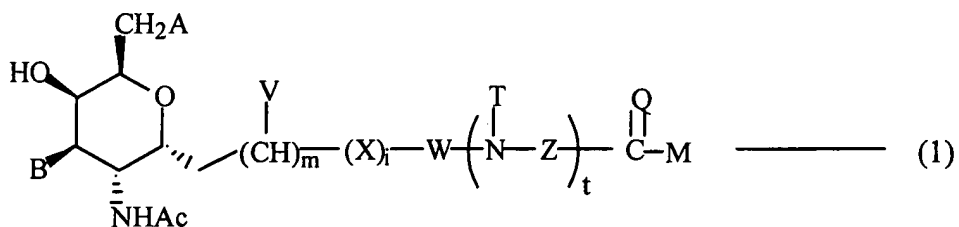
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:) Group Art Unit: 1623
)
TOMIYAMA; UEYAMA; YANAGIYA;) Examiner: Michael C. Henry
OHKURA)
)
Serial No. 09/925,537)
)
Filed: August 10, 2001)
)
For: **NON-MUCIN TYPE SYNTHETIC COMPOUNDS OR ITS CARRIER
CONJUGATED COMPOUNDS**

APPENDIX A

Please amend the claims as indicated according to the July 30, 2003, revision to 37 C.F.R. § 1.121 concerning a manner for making claim amendments.

1. (Currently Amended) A compound of the general formula (1),



wherein

A represents OH or sialic acid and/or it's derivatives ; i and

B represents OH or galactose and/or it's derivatives;

T represents H or protecting groups of amine;

M represents H or OH;

X represents oxygen atom, -NH- or S(O)_z (where z is 0, 1 or 2);

Q is ~~H or~~ oxygen atom and can be present or not present;

V represents lower alkyl or H;

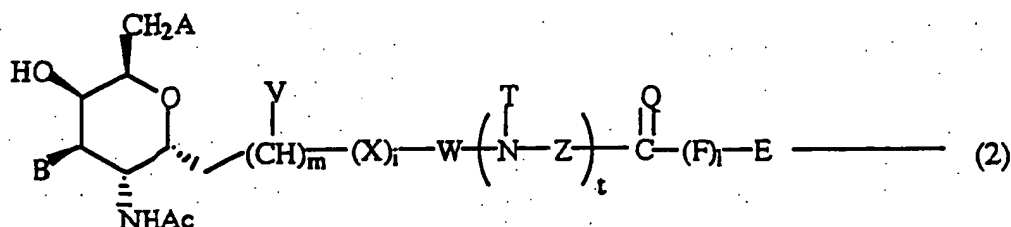
W is straight or branched alkylene groups from 0 to 5;

Z is straight or branched alkylene groups from 1 to 5; and

i, m, and t is 0 or 1 with the proviso that i and t cannot be both 0 +

~~n-mucin type synthetic compounds or it's carrier conjugated compounds, which have above mentioned compounds as a core structure of antigen.~~

2. (Currently Amended) A compound of the general formula (2),



wherein A, B, T, X, ~~Q~~, V, W, Z, i, m, and t have ~~above mentioned~~ meanings;

A represents OH or sialic acid and/or it's derivatives, and

B represents OH or galactose and/or it's derivatives;

T represents H or protecting groups of amine;

X represents oxygen atom, -NH- or S(O)_z (where z is 0, 1 or

2);

Q is oxygen atom and can be present or not present;

V represents lower alkyl or H;

W is straight or branched alkylene groups from 0 to 5;

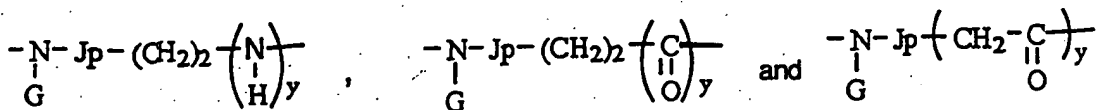
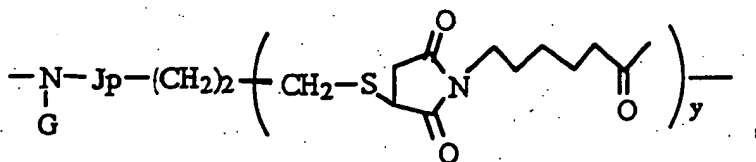
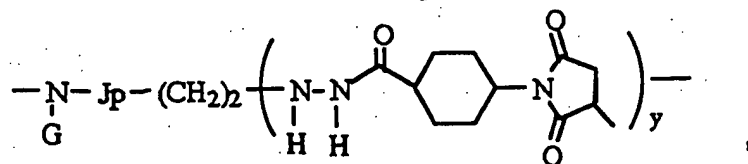
Z is straight or branched alkylene groups from 1 to 5;

i, m, and t is 0 or 1 with the proviso that i and t cannot be both 0;

E represents pharmaceutically acceptable carrier compounds;

l is 0 or 1;

F is showed followings,



J is $\text{--CH}_2\text{CH}_2\text{X--}$ or $\text{--N(L)--CH}_2\text{CO--}$ where X represents oxygen atom, --NH-- or S(O)_z (where z is 0, 1 or 2);

~~(where X have above-mentioned meanings;~~

L is H or lower alkyl + ;

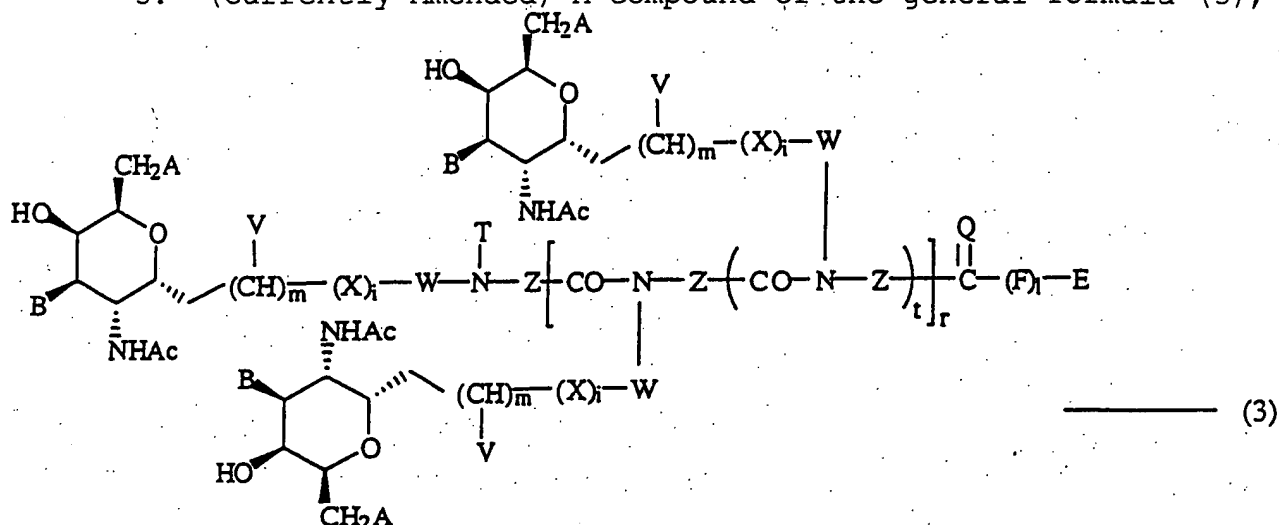
G is H or lower alkyl;

p is 0 to 3; and

y is 0 or 1 +

~~non-mucin type synthetic compounds or it's carrier conjugated compounds, which have above compounds as a core structure of antigen.~~

3. (Currently Amended) A compound of the general formula (3),



wherein A, B, T, X, Q, V, W, Z, i, m, t, E, and l have above-mentioned meanings,

A represents OH or sialic acid and/or it's derivatives, and

B represents OH or galactose and/or it's derivatives;

T represents H or protecting groups of amine;

X represents oxygen atom, -NH- or S(O)₂ (where z is 0, 1 or

2);

Q is oxygen atom and can be present or not present;

V represents lower alkyl or H;

W is straight or branched alkylene groups from 0 to 5;

Z is straight or branched alkylene groups from 1 to 5;

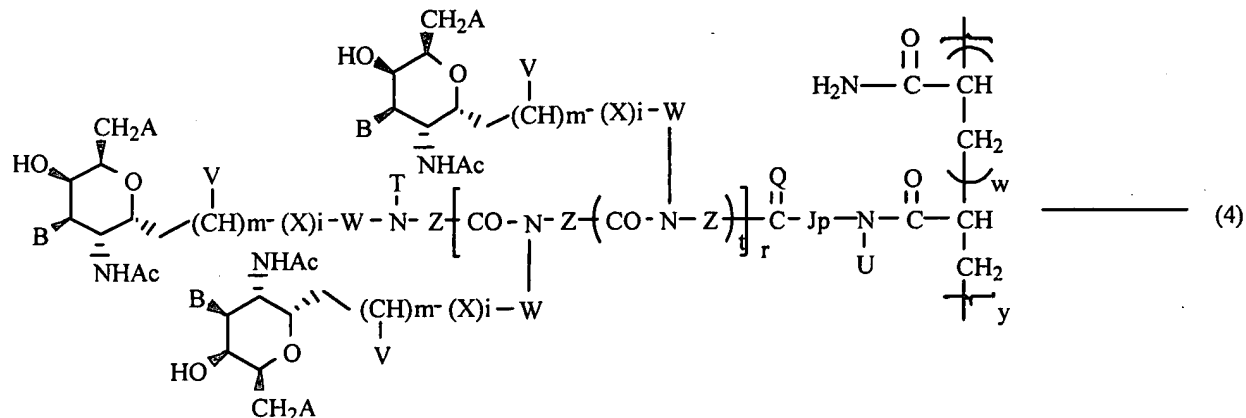
i, m, and t is 0 or 1;

E represents pharmaceutically acceptable carrier compounds;

l is 0 or 1; and

~~r is from 1 to 4 ; non-mucin type synthetic compounds or it's carrier conjugated compounds, which have above compounds as a core structure of antigen.~~

4. (Currently Amended) A compound of the general formula (4),



~~wherein A, B, T, X, Q, V, W, Z, J, i, m, t, p, and r, have above-mentioned meanings;~~

A represents OH or sialic acid and/or it's derivatives, and

B represents OH or galactose and/or it's derivatives;

T represents H or protecting groups of amine;

X represents oxygen atom, -NH- or S(O)_z (where z is 0, 1 or

2);

Q is oxygen atom and can be present or not present;

V represents lower alkyl or H;

W is straight or branched alkylene groups from 0 to 5;

Z is straight or branched alkylene groups from 1 to 5;

J is -CH₂CH₂X- or -N(L)-CH₂CO- where X represents oxygen atom,
-NH- or S(O)_z (where z is 0, 1 or 2);

i, m, and t is 0 or 1;

p is 0 to 3;

r is from 1 to 4;

U represents H or lower alkyl;

w is 0 to 50; and

y is 1 or 50.

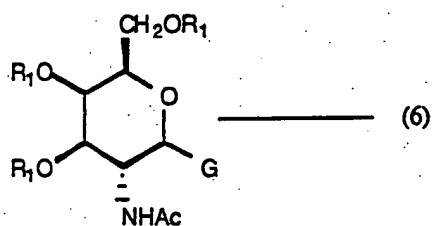
5. (Canceled)

6. (Canceled)

7. (Canceled)

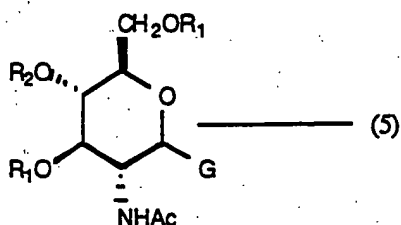
8. (Withdrawn) A process for the preparation of a galactopyranose, which propaty of inversion of OR₂ to OR₁ in above

mentioned glucopyranose derivatives to obtain a compound of the general formula (6)



wherein R₁ is H or a protecting group, such as acetyl, of a hydroxy group; G is allyl or a protected hydroxyl group,

comprising inverting stereochemically OR₂ of general formula (5)



wherein OR₁ is H or protecting group of a hydroxy group such as acetyl group; R₂ is leaving group such as tosylate, trifluoromesylate or methanesulfonate; G is allyl or protected hydroxyl group.

9. (Canceled)

10. (Canceled)

11. (Canceled)

12. (Canceled)

13. (Canceled)

14. (Canceled)

15. (Canceled)

16. (Canceled)

17. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 1, wherein A is
sialic acid and/or its derivatives and B is OH.

18. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 2, wherein A is
sialic acid and/or its derivatives and B is OH.

19. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 3, wherein A is
sialic acid and/or its derivatives and B is OH.

20. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 4, wherein A is
sialic acid and/or its derivatives and B is OH.

21. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 1, wherein A is OH

and B is galactose and/or its derivatives.

22. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 2, wherein A is OH
and B is galactose and/or its derivatives.

23. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 3, wherein A is OH
and B is galactose and/or its derivatives

24. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 4, wherein A is OH
and B is galactose and/or its derivatives

25. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 1, wherein both A
and B are OH.

26. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 2, wherein both A
and B are OH.

27. (Currently Amended) The ~~non-mucin type synthetic compound~~

~~or carrier conjugated~~ compound thereof of claim 3, wherein both A and B are OH.

28. (Currently Amended) The ~~non-mucin type synthetic compound~~
~~or carrier conjugated~~ compound thereof of claim 4, wherein both A and B are OH.

29. (Withdrawn) Immunotherapy using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1.

30. (Withdrawn) Immunotherapy using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2.

31. (Withdrawn) Immunotherapy using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3.

32. (Withdrawn) Immunotherapy using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4.

33. (Withdrawn) Monoclonal antibodies prepared using the non-

mucin type synthetic compound or carrier conjugated compound thereof of claim 1.

34. (Withdrawn) Monoclonal antibodies prepared using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2.

35. (Withdrawn) Monoclonal antibodies prepared using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3.

36. (Withdrawn) Monoclonal antibodies prepared using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4.

37. (Withdrawn) Antitumor agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1 as an active ingredient.

38. (Withdrawn) Antitumor agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2 as an active ingredient.

39. (Withdrawn) Antitumor agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3 as an active ingredient.

40. (Withdrawn) Antitumor agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4 as an active ingredient.

41. (Withdrawn) Tumor immunostimulant containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1 as an active ingredient.

42. (Withdrawn) Tumor immunostimulant containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2 as an active ingredient.

43. (Withdrawn) Tumor immunostimulant containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3 as an active ingredient.

44. (Withdrawn) Tumor immunostimulant containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4 as an active ingredient.

45. (Withdrawn) Anti human immunodeficiency virus (HIV) agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1 as an active ingredient.

46. (Withdrawn) Anti human immunodeficiency virus (HIV) agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2 as an active ingredient.

47. (Withdrawn) Anti human immunodeficiency virus (HIV) agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3 as an active ingredient.

48. (Withdrawn) Anti human immunodeficiency virus (HIV) agents containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4 as an active ingredient.

49. (Withdrawn) An immunostimulant for human immunodeficiency virus (HIV) containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1 as an active ingredient.

50. (Withdrawn) An immunostimulant for human immunodeficiency

virus (HIV) containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2 as an active ingredient.

51. (Withdrawn) An immunostimulant for human immunodeficiency virus (HIV) containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3 as an active ingredient.

52. (Withdrawn) An immunostimulant for human immunodeficiency virus (HIV) containing the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4 as an active ingredient.

53. (Withdrawn) A therapeutic method for tumor treatment using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1 as an active ingredient.

54. (Withdrawn) A therapeutic method for tumor treatment using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2 as an active ingredient.

55. (Withdrawn) A therapeutic method for tumor treatment

using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3 as an active ingredient.

56. (Withdrawn) A therapeutic method for tumor treatment using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4 as an active ingredient.

57. (Withdrawn) A therapeutic method for treatment of HIV using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 1 as an active ingredient.

58. (Withdrawn) A therapeutic method for treatment of HIV using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 2 as an active ingredient.

59. (Withdrawn) A therapeutic method for treatment of HIV using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 3 as an active ingredient.

60. (Withdrawn) A therapeutic method for treatment of HIV using the non-mucin type synthetic compound or carrier conjugated compound thereof of claim 4 as an active ingredient.

61. (New) The compound of the general formula (1) of claim 1, further comprising a pharmaceutically acceptable carrier conjugated to said compound of the general formula (1).